UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,930	04/25/2001	Paul H. Weigel	5820.603	1177

30589 7590 04/29/2002

DUNLAP CODDING & ROGERS P.C.
SUITE 420
9400 N. BROADWAY
OAKLAHOMA CITY, OK 73114

EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED ST[illegible]S DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	

ART UNIT	PAPER NUMBER
	9

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire One month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-87 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-87 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
[illegible]w Summary, PTO-413
[illegible]tsperson's Patent Drawing Review, PTO-948
[illegible]Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1996-421-632/40206

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to anti-HARE antibodies, classified in class 530, subclass 387.1.

II. Claims 19-47, drawn to HARE protein and fragments thereof, classified in class 530, subclass 350.

III. Claims 48-74, drawn to nucleic acids, vectors, and expression methods, classified in class 435, subclass 69.1.

IV. Claims 75-~~86~~ 87, drawn to binding assays using protein, classified in class 435, subclass 7.1.

10 4/25/07

The inventions are distinct, each from the other because:

The polypeptide of Invention II is related to the antibody of Invention I by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The nucleic acid of Invention III is distinct from and unrelated to the antibody of Invention I because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention III is distinct from and unrelated to the antibody of Invention I because the antibody may be neither made by nor used in the method.

The products of invention I are separate and distinct from the methods of invention IV wherein the products are neither made by nor required for the methods, and wherein the two inventions require separate, divergent searches.

The polypeptide of Invention II is related to the nucleic acids of Invention III by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of invention II may be used in a process of making the antibodies of invention I.

The products of invention III are separate and distinct from the methods of invention IV wherein the products are neither made by nor used in the methods. The methods of invention II are separate and distinct from the methods of invention IV wherein the two sets of methods have different active agents, utilities and method steps, and require non-coextensive searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Election of Species Requirement:

In addition to the above restriction requirement, an election of species is required for each of inventions I-III.

This application contains claims directed to the following patentably distinct species of the claimed invention:

In the case of Invention I: SEQ ID NO: 2 and SEQ ID NO: 25.

In the case of Invention II: (a) SEQ ID NO: 2 and SEQ ID NO: 25.

Also in the case of Invention II: (b) mAb-28, mAb-30, mAb-54, mAb-154, mAb-159, mAb-174, mAb-235, and mAb-467.

In the case of Invention III: SEQ ID NO: 1, SEQ ID NO: 24, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, and SEQ ID NO: 6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Note that there are two independent requirements for election of species in the case of Invention II.

Currently, the following claims are generic:

Invention I: 1-4, 7 and 10-18.

Invention II, species election (a): 19, 21-23, 32-36, 41, 43-46.

Invention II, species election (b): 19-21, 24-31, 37-41, 42-47.

Invention III: 48, 55, 59-60, 62-67.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

To be fully responsive to this action, applicants must elect both an invention, and, for that invention, the appropriate election of species (there being two such species requirements for Invention II, and none for Invention IV), as well as a listing of all claims readable upon the elected

invention and species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/842930.r
4/25/02